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| 10/815,425 | 03/31/2004 | Bruce D. Hammock | 02307O-142500US | 8475 |

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| EXAMINER | |
|---|---|
| POLANSKY, GREGG | |
| **ART UNIT** | **PAPER NUMBER** |
| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/815,425 | HAMMOCK ET AL. | |
| | Examiner | Art Unit | |
| | GREGG POLANSKY | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *9-50* is/are pending in the application.

4a) Of the above claim(s) *11-13,19-24,27-29 and 35-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10,14-18,25,26 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/2008 & 2/04/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of Claims

1. Applicants' amendment, filed 11/29/2007, adding Claims 41-50, is acknowledged.

2. Applicants' Information Disclosure Statements, filed 1/30/2008 and 2/04/2008, are acknowledged and have been reviewed to the extent each is a proper citation on a U.S. Patent.

3. Applicants' election without traverse of Group I (Claims 9, 10, 14-18, 25, 26 and 30-34) in the reply filed on 11/29/2007 is acknowledged. Applicants further elect the species obstructive pulmonary disease, adamantly dodecyl ureas, and 14,15-EET, also without traverse. The Restriction Requirement is thus deemed to be proper and is made Final.

4. Claims 9-50 are pending.

5. Claims 11-13, 19-24, 27-29 and 35-50 are withdrawn from consideration in accordance with 37 CFR 1.142(b) because they are contained in non-elected groups and/or read on non-elected species.

6. Claims 9, 10, 14-18, 25, 26 and 30-34 are presently under consideration.

7. Applicant's arguments with respect to Claims 9, 10, 14-18, 25, 26 and 30-34 have been considered but are moot in view of the new grounds of rejection.

8. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 9, 10, 14-18, 25, 26 and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammock et al. (U.S. Patent Application Pub. No. 2005/0026844 A1)

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hammock et al. teach inhibitors of soluble epoxide hydrolase ("sEH"), alone and in combination with *cis*-epoxyeicosantrienoic acids ("EET"), in methods of inhibiting progression of obstructive pulmonary diseases, including chronic obstructive pulmonary

disease. The reference teaches *inter alia* adamantly dodecyl urea sEH inhibitors and 14,15-EET (including 14R,15S-EET). See Abstract; Figure 1, compounds 192 and 686; page 2, paragraph 18; pages 6-7, particularly paragraph 71; page 9, paragraph 100; page 16, Example 6; and page 48, claims 48, 49, 51, and 52. Hammock et al. teach slow release formulations of the disclosed compositions. See page 9, paragraph 104. Further, the reference teaches wide oral dose ranges (e.g., 2-2000 mg/day, or 0.05 mg/kg to 20 mg/kg per day). However, Hammock et al. disclose that the "dose, frequency and timing of " the administration of the compositions "will depend in large part on the selected therapeutic agent, the nature of the condition being treated, the condition of the subject including age, weight and presence of other conditions or disorders, the formulation being administered and the discretion of the attending physician". See page 8, paragraph 94.

Hammock et al. teach all the limitations of the instant claims and thus clearly anticipate the instant invention.

***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 9, 10, 14-18, 25, 26 and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 111, 112, 115, 120-122 of copending Application No. 11/685674. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods of treating lung disease with the administration of soluble epoxide hydrolase inhibitors, including those recited by the instant claims. Although the conflicting claims do not recite the administration of EETs with the sEH inhibitors, the specification discloses its use and the claim language is open, thus allowing the inclusion of additional agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 9, 10, 14-18, 25, 26 and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 10, 11 and 20 of copending Application No. 11/566171. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods of treating inflammation, including inflammatory disorders of the lungs, with the administration of soluble epoxide hydrolase inhibitors, including those

recited by the instant claims. Although the conflicting claims do not recite the administration of EETs with the sEH inhibitors, the claim language is open, thus allowing the inclusion of additional agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 9, 10, 14-18, 25, 26 and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 10, 11 and 21-23 and 26 of copending Application No. 11/240444. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods of treating inflammation, including inflammatory disorders of the lungs, with the administration of soluble epoxide hydrolase inhibitors, including those recited by the instant claims. Although the conflicting claims do not recite the administration of EETs with the sEH inhibitors, the claim language is open, thus allowing the inclusion of additional agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. It is requested that the Applicants provide a listing of all related co-pending applications and patents. Additional double patenting rejections may be forthcoming.

***Conclusion***

16. Claims 9, 10, 14-18, 25, 26 and 30-34 are rejected.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregg Polansky

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